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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/681,878

10/09/2003

Vincent L. Chiang

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FOLEY AND LARDNER LLP  
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WASHINGTON, DC 20007

EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

11/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/681,878

### Applicant(s)

CHIANG ET AL.

### Examiner

Stuart F. Baum

### Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/9/2003 & 6/29/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. The amendment filed 8/29/2007 has been entered.
2. Claims 27 and 29 are pending.  
Claims 1-26 and 28 have been canceled.
3. Applicants have amended claim 27 to be drawn to SEQ ID NO:10 and have traversed the withdrawal of said claim as indicated in the office action mailed 5/30/2007.
4. Claims 27 and 29, including SEQ ID NO:10 are examined in the present office action.
5. Rejections and objections not set forth below are withdrawn.
6. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

***New Matter***

7. Claim 29 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/30/2007. Applicant's arguments filed 8/29/2007 have been fully considered but they are not persuasive.

Applicants contend support for "wherein said promoter region directs gene expression and includes two GGTAGGTA binding sites" can be found, *inter alia* in paragraph [0045]

Art Unit: 1638

bridging pages 9-10, in Figure 6 and in SEQ ID NO:10 (paragraph bridging pages 5 and 6 of Remarks).

The Office contends the specified locations within the specification filed 6/29/2006 do not explicitly point out two binding sites with the specified sequence. The Office contends the two GGTAGGTA binding sites were not previously contemplated at the time of filing.

### ***Written Description***

8. Claim 29 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 1/30/2006 and 5/30/2007. Applicant's arguments filed 8/29/2007 have been fully considered but they are not persuasive.

Applicants contend they have sufficiently disclosed the invention to meet the written description requirement in line with the reasoning provided by the Federal Circuit (page 7 of Remarks, 3<sup>rd</sup> full paragraph). Applicants state "With regards to recitation of known structure, Faulkner explicitly holds: "it is the binding precedent of this court that Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art."" (page 7 of Remarks, 2<sup>nd</sup> full paragraph).

The Office contends that Applicants have not disclosed a representative number of sequences comprising a fragment of SEQ ID NO:10 which comprises two GGTAGGTA binding

Art Unit: 1638

sites and has the required promoter activity, nor have Applicants disclosed essential regions other than the two GGTAGGTA binding sites which are required for the required promoter activity.

Applicants have only disclosed one sequence of SEQ ID NO:10.

### ***Enablement***

9. Claim 29 remains rejected and claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 1/30/2006 and 5/30/2007. Applicant's arguments filed 8/29/2007 have been fully considered but they are not persuasive.

Applicants state "Specifically, the Office action recognizes that the specification provides enablement for the promoter region of the 4CL gene having SEQ ID NO:10" (page 8 of Remarks, 2<sup>nd</sup> paragraph).

The Office contends that it **does not** recognize that the specification provides enablement for the promoter region of the 4CL gene having SEQ ID NO:10.

Applicants contend amended claim 29 is directed to a specific 4CL promoter region that is essential for correct promoter activity (page 9 of Remarks, 1<sup>st</sup> full paragraph).

The Office contends Applicants have only disclosed SEQ ID NO:10 and a method for isolating said sequence. Applicants have not disclosed if in fact SEQ ID NO:10 comprises the necessary elements essential and sufficient for promoter activity. Applicants have not disclosed the spatial and temporal expression pattern that is the result of the promoter activity of SEQ ID

Art Unit: 1638

NO:10. In fact, Applicants have not disclosed if the isolated promoter has any promoter activity at all. Therefore, given the state-of-the-art, and unpredictability as stated in the office action 1/30/2006, Applicants are not enabled for the claimed invention. The Office notes that the Rottmann §1.132 Declaration filed 3/20/2007 is drawn to SEQ ID NO:11 and not the instantly claimed invention of SEQ ID NO:10.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.


Art Unit: 1638

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stuart F. Baum Ph.D.  
Primary Examiner  
Art Unit 1638  
November 8, 2007

  
STUART F BAUM, PH.D.  
PRIMARY EXAMINER